

Remarks

The Examiner's analysis and remarks set forth in the Office Action are noted with appreciation. Reconsideration of the application is requested in view of the foregoing amendments and the following remarks.

The Examiner has acknowledged that Elsberry does not disclose a hollow rigid tube having a remotely detectable locator that allows the stylet to be tracked by a positioning system. In view of this, the Examiner looks to Thomas for a disclosure of a stylet having a radiopaque material at the tip allowing the stylet to be tracked and viewed radiographically when positioned in the patient's body. The Examiner also observed that the locator and positioning system were being broadly claimed without specifics as to the nature of the positioning system.

Thomas discloses an obturator for use with an access device. Thomas, in the background section, states:

Access to the vascular or other systems within the body of a living being are now being provided by many types of minimally invasive devices, such as needles, sheath introducers, catheters, etc. Often the procedure involved in providing access to the interior of the being's body requires the maintenance of the access device's lumen in position, e.g., within the interior of an artery, while providing a secure closure at the proximal fitting of the device, e.g., to prevent the egress of blood therefrom. In order to effect that secure closure, conventional devices, such as obturators, have been used in the access device's lumen. Such obturators typically comprise an elongated, rod-like element which when extended into the lumen of the access device protrude slightly beyond its distal (open) end. The obturator is held in place in the lumen via an appropriate fitting cooperating with a fitting on the access device. In order to facilitate the placement of the obturator within the access device, the obturator is typically formed of a relatively rigid material so that its tip is rigid or hard. Thus, when such a prior art obturator is used it may traumatize the tissue which is engaged by the rigid tip, particularly if the obturator is left in place (indwells) for an extended period of time. (emphasis added)

Accordingly, the focus of Thomas is on an obturator that is intended to extend beyond the lumen into which it is inserted. With that in mind, it is not seen why the skilled person would look to Thomas since Elsberry provides a closed tip 26 for the catheter as shown in Fig. 3 of Elsberry.

Even assuming there was some reasonable basis to conclude that the skilled person would have looked to Thomas for improvements in the device of Elsberry, any resultant combination still would not yield the subject matter of the claims, particularly as amended.

According to Thomas, "conventional obturators have included radiopaque materials therein, e.g., barium sulfate, in order to enable the user to radiographically image the device to determine its placement within the body. Radiography is the use of X-rays to view unseen or hard-to-image objects. Once the obturator has been placed, an x-ray device is used to produce a radiograph so that one can determine the placement of the obturator tip within the body. If not in the correct position, presumably the obturator would be repositioned, and then another radiograph is taken using the x-ray device.

Image-guided surgery, on the other hand, is a surgical procedure where the surgeon uses indirect visualization to operate, i.e., by employing imaging instruments in real time. Existing IGS systems use different tracking techniques including mechanical, optical, ultrasonic, and electromagnetic. See *Wikipedia*.

The independent claims have been amended to recite in more definitive terms real time, or online, tracking versus offline position detection according to Thomas. Consequently, the combination advanced by the Examiner would not yield the subject matter of the claims as amended.

Looking at claim 1 in particular, the claimed system comprises, *inter alia*, a positioning system that can be coupled to an image-guided surgical workstation; and a remotely detectable locator on the hollow rigid tube trackable by the positioning system as the hollow rigid tube is tunneled through tissue in the patient's body toward the target location whereby the progress of the locator can be tracked and thus the position of the hollow rigid tube can be positionally tracked by the positioning system for proper positioning of the infusion catheter in relation to the patient's body into which the hollow rigid tube and catheter have been inserted and displayed on a monitor of the image-guided surgical workstation. That is, the position of the remotely detectable locator is tracked as the rigid tube is tunneled through the tissue in the patient's body. Neither Elsberry nor Thomas offer any suggestion of this real time tracking.

This same distinction is shared with the other independent claims as amended. The system of claim 16 comprises, *inter alia*, a positioning system that can be coupled to an image-guided surgical workstation; and a remotely detectable locator on the

hollow rigid tube trackable by the positioning system as the hollow rigid tube is tunneled through tissue in the patient's body toward the target location. The method of claim 18 comprises, *inter alia*, the directing step to include using a positioning system to track the progress of a locator on the rigid tube as the rigid tube is tunneled through tissue in the patient's body toward the target for proper guidance of the infusion catheter to the target. The system of claim 24 comprises, *inter alia*, locator means on the hollow stylet means for enabling the catheter to be tracked by a positioning system coupled to an image-guided workstation as the hollow stylet means is being tunneled through tissue in the patient's body toward the target location when one or more locators are attached to at least one of the catheter and hollow stylet means.

For at least the foregoing reasons, the rejections should be withdrawn.

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

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